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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,498

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Xu Zhang

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

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06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,498	Applicant(s) ZHANG ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008 and 15 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8 and 10-56 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 34-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,10-33 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/15/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

ETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/2008 has been entered.
2. Amendment of claims 1 and 8 and cancellation of claim 7 in the filing of 3/12/2008 is acknowledged. Claims 1, 2, 8, 10-33 and 56 are pending and examined herein; claims 3-4 and 34-55 were previously withdrawn from examination.

Specification

3. The disclosure is objected to because of the following informalities:

The use of the trademark eppendorf has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Rejection of claims 1, 2, 10, 11, 13-17, 22-28, 31-33 and 56 under 35 U.S.C. 102(b) as being anticipated by Jenssen and Rios is **withdrawn** in view of amendment of claims 1 and 8; rejection of claim 7 is moot and **withdrawn** in view of cancellation of the claim.
5. Rejection of claims 1, 2, 10, 11, 13-17, 22-26 and 56 under 35 U.S.C. 102(b) as being anticipated by Fletcher is **withdrawn**; rejection of claim 7 is moot and **withdrawn** in view of cancellation of the claim. Inclusion of the rejection in the previous Office Action was a clerical error substituting a preliminary and draft Office action for the final Office action by the Examiner. The Examiner regrets the error and confusion to the prosecution of the instant Application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Rejection of claims 10, 12, 16, 17 and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over either Jenssen or Fletcher in view of Ullman is **withdrawn** in view of amendment to claim 1.
7. Claims 1, 2, 8, 10-33 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher, et al. in view of Kemshead and Ugelstad and Rudi, et al. The claims are drawn to a method of cell separation that excludes specific binding pair interaction and includes permanent magnetic microbeads. Further limitations of the basic method specifies the type of cell or virus (claims 2 and 27), the type of alloy (claim 8), the size of the beads (claim 10), treatment or modification of the microbead (claim 11) the nature of modification of the microbead (claim 12), an additional washing step to remove undesirable constituents (claims 13, 31-32 and 56), an additional recovery step (claims 14, 15 and 33), the nature of the sample (claims 16-17 and 27-29), an additional step of recovering a biological material from the target (claims 18-19), the additional step of amplifying recovered oligonucleotide (claim 20), automation of the process (claim 21), time of completion of the process (claim 22), absence of a precipitation step (claim 24) or poisonous agent (claim 25), ambient temperature during procedure (claim 26), pH range and presence of anticoagulant (claims 29-30).

Fletcher, et al. teaches a method of recovery of marine bacteria from environmental samples using the well-known property inherent in polystyrene to non-specifically affix proteins and cells to the surface. Of particular note is the

teaching that the so-called panning method allows isolation and subsequent identification of bacterial from relatively large amounts of environmental samples. Fletcher, et al. is used herein solely to establish that it has long been known that untreated polystyrene per se is useful for non-specific biological sample concentration resulting in viable organisms. Fletcher, et al. does not teach microbeads nor any of the limitations outlined above.

Kemshead and Ugelstad teach the use of magnetic materials for medical applications. As one of the pioneer inventors of magnetic microbeads, Ugelstad is responsible for ensuring the size homogeneity of polymeric magnetic microbeads and inclusion of derivatized magnetic microbeads further useful in medically relevant treatment and diagnostic methods as well as usefulness in basic medical research. Kemshead and Ugelstad specifically teach separation methods using magnetic microbeads for a variety of cell types using both non-specific binding (see, for example, section II. Ways of generating magnetic cells) and specific binding partners (see, for example, section III. Targeting 'magnetic material' to cells). Thus, the combination of Fletcher, et al. and Kemshead and Ugelstad teach that many types of cells, and especially environmental cells, can be separated and enriched from dilute environmental and clinical samples using magnetic polystyrene beads under a wide variety of conditions. Finally, Rudi, et al. teaches a method of using magnetic microbeads to sequentially separate bacteria from environmental samples and amplify separated DNA using the same magnetic microbeads.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Fletcher, et al. by substituting unmodified magnetic microbeads for polystyrene Petri dishes as taught by Kemshead and Ugelstad and/or Rudi, et al. The skilled artisan would have been motivated to do so because of the nonspecific adhesion of cells to polystyrene as taught by Fletcher, et al. and the rapidity of magnetic bead separation as taught by Kemshead and Ugelstad and/or Rudi, et al. There would have been a reasonable expectation of success, given well-known absorptive properties of polystyrene, as taught by Fletcher, et al. and the general utility of magnetic bead separation methods as taught by many researchers especially including Kemshead and Ugelstad and/or Rudi, et al. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, 8, 10-33 and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for several of the recited magnetizable substances, does not reasonably provide enablement for those comprised of copper, tantalum or zirconium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to practice the invention commensurate in scope with these claims.

This is a “scope of enablement rejection”.

Claim 1 is drawn to a method of separating cells, cellular organelles and viruses from samples using magnetic microbeads not comprising moieties comprising specific binding pairs and comprising "a magnetizable substance selected from the group consisting of a ferromagnetic substance, a ferrimagnetic substance~ and nickel, copper, tantalum, zirconium and an alloy thereof"; the remaining claims depend directly or indirectly on claim 1. It is well known that at room temperature or those temperatures normally associated with cell separation methodologies only three transition metals are ferromagnetic: Iron, cobalt and nickel. Although tantalum and zirconium have non-zero magnetic moments, the temperatures at which they have such properties are near 15 K; copper is not known to exhibit magnetic behavior except in the instance of electromagnets and it is not taught in the specification how to make a nanoelectromagnet using copper. Thus, the specification and general knowledge in the art would allow a skilled artisan in the area of cell separation using magnetic microbeads to practice the method with known ferromagnetic and ferrimagnetic substances including magnetite, nickel and alloys of tantalum and zirconium, but not with the pure metals copper, tantalum and zirconium.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 contains the trademark/trade name eppendorf. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymeric microcentrifuge tube and, accordingly, the identification/description is indefinite.

Conclusion

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS